



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
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Atlanta, GA 30341-3724

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Deputy Assistant Secretary of the Navy
Environment
1000 Nay Pentagon
Washington, D.C. 20350-1000

Lt. General Frank A. Panter
Deputy Commandant, Installations and Logistics
3000 Marine Corps, Pentagon, Room 4E516
Washington, D.C. 20350-3000

Dear Mr. Schregardus and Lt. General Panter:

I recently met with Senator Kay Hagan (D-NC) regarding our work on the potential for health effects from exposure to contaminated drinking water at Marine Corp Base Camp Lejeune (Camp Lejeune). During our conversation, it became evident that there was still some confusion regarding the position of the ATSDR regarding the 2009 National Research Council (NRC) report, *Contaminated Water Supplies at Camp Lejeune – Assessing Potential Health Effects*. Because of our collaboration and joint concern regarding exposures to military personnel, their families and others at Camp Lejeune, I wanted to be certain you understood our position regarding this report. This letter is intended to clarify our position and to provide a brief explanation on how we reached this position.

There is one constraint and five conclusions in the NRC report that are essential to the issue of whether harm may be expected in populations exposed to Camp Lejeune contaminated drinking water. These relate to:

1. the contaminants and health outcomes considered by the NRC;
2. the dose-response assessment used by the NRC;
3. the water modeling for Tarawa Terrace published by the ATSDR;
4. the use of alternative modeling strategies;
5. the need for detailed statistical analysis plans;
6. the utility of the epidemiological studies proposed by the ATSDR.

I will address each of these issues in sequence.

The NRC report only focused on tetrachloroethylene (PCE) and trichloroethylene (TCE), without considering other drinking water contaminants at Camp Lejeune such as benzene, vinyl chloride and mixtures of volatile organic compounds (VOCs). As noted in the very recent International Agency for Research on Cancer (IARC) Monograph Volume 100, benzene causes acute myelogenous leukemia and is associated with other leukemias. The National Toxicology Program (NTP) Report on Carcinogens (ROC) reaches the same conclusion. Both reports reach a similar conclusion for vinyl chloride with regard to liver tumors. Both the IARC and the NTP label benzene and vinyl chloride as "known human carcinogens". The failure of the NRC Committee to consider these contaminants may lead one to conclude that the NRC findings of "*limited/suggestive evidence of an association*" pertains to all contaminants in the drinking water at Camp Lejeune. This conclusion would be incorrect based upon the evidence of the occurrence of these other exposures in Camp Lejeune drinking water. Thus, the review of cancer risks by the NRC was incomplete and only partially addressed concerns at Camp Lejeune. Finally, the NRC conclusions for PCE and TCE differ from the NTP and IARC which classify these chemicals as "probable human carcinogens" (IARC) or "reasonably anticipated to be a human carcinogen" (NTP) with various cancers including most notably kidney tumors.

Thus, let me be perfectly clear; there was undoubtedly a hazard associated with drinking the contaminated water at Camp Lejeune. The epidemiological studies and the associated exposure modeling will hopefully help us to decide on the level of risk associated with this hazard.

Although the availability of definitive reviews on other health endpoints besides cancer is limited, another shortcoming of the NRC review pertains to other health outcomes including adverse birth outcomes and immunotoxicity. In deciding what needed to be done to evaluate the potential health effects at Camp Lejeune, the ATSDR has taken all contaminants and all health outcomes into account and is acting accordingly.

ATSDR has studied the NRC report regarding the remaining issues. The use of the "lowest observed adverse effect level" (LOAEL) from animal studies without consideration of the uncertainties inherent in the LOAEL and the appropriateness of the use of this metric for assessing genotoxic cancer risks is a major shortcoming of the NRC report. Most regulatory agencies would either address the uncertainty in the LOAEL through the use of multiplicative factors to reduce the acceptable exposure or use an entirely different metric, such as the slope of the dose-response curve or a confidence bound around this curve, to arrive at values for comparison against environmental exposures. By doing neither, the NRC report suggests a much wider difference between exposure and effect

than would normally be derived. In determining potential risks in order to develop power calculations for our epidemiological investigations, the ATSDR used the slope of the dose-response curve.

ATSDR disagrees with the NRC Committee's conclusion that the results of the water modeling for Tarawa Terrace were not sufficiently reliable to do dose characterization in the epidemiological studies. Modeling of the movement of contaminants through subsurface water is a well established area of science and has been used on multiple occasions to address exposures in communities throughout the United States [reference: Anderson, MP. 1979. Using models to simulate the movement of contaminants through ground water flow systems. *Critical Reviews in Environmental Control*, 9(2): 97-156.] The state-of-the-art modeling being conducted by ATSDR shows sufficient concordance between the modeled PCE results and the actual measurements of PCE in the finished water at Tarawa Terrace to conclude that one could characterize exposure into several different groups. This conclusion is critical to the future epidemiological studies since it allows ATSDR to separate highly exposed individuals from individuals exposed to moderate and/or low exposures from the drinking water thus limiting exposure misclassification and the resulting bias in the direction of no effect on the study populations. Without these different classifications, ATSDR would need to rely on a simple grouping of exposed versus unexposed, severely limiting the utility of the epidemiological evaluations.

ATSDR agrees with the NRC report that, due to the complexity of the situation at Hadnot Point, alternative modeling strategies should be considered. We have addressed this issue in the current modeling activities and are moving forward with a strategy that will yield sufficiently reliable estimates for this complex exposure scenario.

ATSDR also agrees with the NRC recommendation that detailed plans for the statistical analyses should be and have been developed by ATSDR for the re-analysis of the adverse pregnancy outcome study and the birth defect/childhood cancer case-control study. ATSDR disagrees with the NRC that these studies should be completed as soon as possible; data analysis will not proceed until the drinking water modeling has been completed and is available for both Hadnot Point and Tarawa Terrace.

ATSDR disagrees with the NRC report's conclusion that the mortality study and the health survey/morbidity study lack sufficient statistical power and would be so limited by biases that they would not produce useful scientific information or be definitive. In the June 2008 ATSDR report Assessment of the Feasibility of Conducting Future Epidemiologic Studies at USMC Base Camp Lejeune, statistical power calculations were presented showing that the studies would have sufficient power for the cancers of interest, in particular, cancers associated with benzene, vinyl chloride, TCE or PCE exposure such as kidney cancer, non-

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Hodgkin's lymphoma, leukemias, liver cancer, and esophageal cancer. Moreover, ATSDR emphasized that the studies would use standard research methodologies to minimize biases.

ATSDR is proceeding with the USMC Camp Lejeune Mortality Study and the Health Survey. ATSDR will establish a panel of experts to recommend adequate participation rates and consider potential biases in using the health survey for the follow-up morbidity study. We appreciate your financial support for these studies and your cooperation in the Data Discovery Technical Working Group. We are currently working on a request for additional FY 2011 funding requirements which should be completed soon.

Thank you again for your support.

Sincerely,



Christopher J. Portier, Ph.D.
Director, National Center for
Environmental Health, and
Agency for Toxic Substances and
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